

REMARKS

Amendments

In the interest of expediting the prosecution of this Application, Applicant amends Claims 1, 18, 36, 39, and 43, and cancels Claims 16, 19-28, 32-35, and 49-79. Applicant reserves the right to reintroduce the original Claims 1, 16, 18-28, 32-36, 39, 43, and 49-79 in one or more continuation-type application.

Claim 1 is amended to insert the phrase “wherein said pharmaceutical or veterinary composition is an inhalable, respirable, or intrapulmonary formulation” from dependent Claim 35. Support for the amendment is found, for example, from Claim 35 as originally filed.

Claim 18 is amended to delete the term “topical”. Support for the amendment is found, for example, from Claim 18 as originally filed.

Claim 36 is amended to delete the term “spray”. Support for the amendment is found, for example, from Claim 36 as originally filed.

Claim 36 is amended to depend from Claim 1 instead of Claim 35. Canceled Claim 35 depended from Claim 1, and the limitations of Claim 35 have been incorporated into amended Claim 1. Support for the amendment is found, for example, from Claims 1, 35, and 36 as originally filed.

Claim 39 is amended to delete the term “nasal”. Support for the amendment is found, for example, from Claim 39 as originally filed.

Claim 46 is amended to delete the phrase “the composition comprises inhalable, respirable, intrapulmonary or nasal formulation”. This phrase is deleted because the limitations have been added to Claim 1, from which Claim 39 depends. Support for the amendment is found, for example, from Claims 35 as originally filed.

Response

Claims 1-15, 17, 18, 29-31, and 36-48 are pending in the present application.

Claims 16, 19-28, 32-35, and 49-79 are canceled.

1. Request for withdrawal of finality.

The Examiner asserts that the rejections of the Office Action dated October 1, 2003 are “necessitated by Applicant’s amendment filed on July 9, 2003 . . . wherein the limitations in all pending claims as amended now have been changed since the recitation “optionally” in claim 1 has been deleted” (page 2, lines 15-17).

The term “optionally” has the meaning of “something chosen or available as a choice” (see Definition 4 of “option” in The American Heritage Dictionary 2d College Ed.; a copy of which is attached). In claim 1, prior to the amendment of July 9, 2003, described a pharmaceutical or veterinary composition comprising a dehydroepiandrosterone **and/or** a ubiquinone. The amendment of July 9, 2003 deleted the term “optionally” which then rendered claim 1 to describe a pharmaceutical or veterinary composition comprising a dehydroepiandrosterone **and** a ubiquinone. Thus, the subject matter of amended claim 1 was in fact specifically claimed by the claim 1 prior to the amendment.

Therefore, the 35 U.S.C. §§ 102(b) and 103 rejections of the Office Action are new grounds of rejection that are not necessitated by the July 9, 2003 amendment of Claim 1.

Further, the Examiner asserts a new double patenting rejection over Claim 159 of copending Application Ser. No. 10/072,010. This is a new ground of rejection that is also not necessitated by the July 9, 2003 amendment of Claim 1.

For the reasons stated above, Applicant respectfully requests the Examiner to withdraw the finality of this Office Action.

2. 35 U.S.C. §102(b).

The Examiner rejects Claims 1-15, and 17-41 under 35 U.S.C. §102(b) as allegedly being anticipated by Nyce (U.S. Patent No. 5,527,789; hereafter, the ‘789 patent). Applicant traverses this rejection of Claims 1-15, 17, 18, 29-31, and 36-41. Claims 19-28, and 32-35 are canceled.

Claim 1 is amended to include the limitation that the pharmaceutical or veterinary composition is an inhalable, respirable, or intrapulmonary formulation. The ‘789 patent discloses the use of dehydroepiandrosterone (“DHEA”) and/or ubiquinone to combat cancer. The ‘789 discloses formulations of DHEA and/or ubiquinone “suitable for oral, rectal, topical, transdermal, nasal, ophthalmic or parenteral (including subcutaneous, intramuscular and

intravenous) administration” (col. 6, lines 40-43). However, the ‘789 patent does **not** disclose DHEA and ubiquinone in an inhalable, respirable, or intrapulmonary formulation. Further, the ‘789 patent does **not** disclose the formulation in particles sizes of about 0.05 to about 10 μm (as claimed in Claim 37), about 0.1 to about 5 μm (as claimed in Claim 38), about 10 to about 100 μm (as claimed in Claim 39), or about 10 to about 50 μm (as claimed in Claim 40). In fact, the ‘789 patent does not disclose DHEA and ubiquinone in any particle size. Since the ‘789 patent does not disclose DHEA and ubiquinone in an inhalable, respirable, or intrapulmonary formulation, therefore the ‘789 patent does not anticipate Claim 1, and Claims 2-15, 17, 18, 29-31, and 36-41, which depend from Claim 1.

Therefore, the ‘789 patent does not anticipate Claims 1-15, 17, 18, 29-31, and 36-41. Thus, the Examiner is respectfully requested to withdraw this basis of rejection.

3. 35 U.S.C. § 103(a)

The Examiner rejects Claims 42-48 under 35 U.S.C. § 103(a) as allegedly being rendered obvious over the ‘789 patent. Amended Claims 42-48 are directed to a kit comprising a composition comprising a DHEA having the chemical formula (I) and a ubiquinone, wherein the composition is an inhalable, respirable, or intrapulmonary formulation. As explained above, the ‘789 patent does not disclose DHEA and ubiquinone in an inhalable, respirable, or intrapulmonary formulation.

MPEP 2143.3 states: “To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested in the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).” Since an inhalable, respirable, or intrapulmonary formulation is neither taught nor suggested by the ‘789 patent, the Examiner has not established *prima facie* obviousness of Claims 42-48 over the ‘789 patent.

Since a *prima facie* case of obviousness has not been made for Claims 42-48, the Examiner is respectfully requested to withdraw this rejection.

4. Double Patenting

The Examiner rejects Claims 1-15 and 17-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 13-19 of U.S. Patent No. 5,527,789. In the interest of expediting prosecution of the present application, Applicant will

submit a properly executed Terminal Disclaimer to overcome this rejection when there are any otherwise allowable claims.

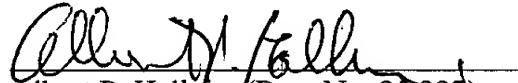
The Examiner provisionally rejects Claims 1-15 and 17-48 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 159 of copending Application Ser. No. 10/072,010. In the interest of expediting prosecution of the present application, Applicant will submit a properly executed Terminal Disclaimer to overcome this rejection when there are any otherwise allowable claims.

CONCLUSION

In view of the foregoing amendment and remarks, the Applicant believes that the application is in good and proper condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned at (650) 463-8109.

Respectfully submitted,

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Albert P. Halluin, (Reg. No. 25,227)
Robin C. Chiang (Reg. No. 46,619)

HOWREY SIMON ARNOLD & WHITE, LLP
301 Ravenswood Avenue
Box 34
Menlo Park, CA 94025
(650) 463-8109